

§810.16

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(3) That health professionals and device user facilities should cease use of the device immediately;

(4) Where appropriate, that the device is subject to a mandatory recall order; and

(5) Specific instructions on what should be done with the device.

(b) *Implementation.* The person named in a cease distribution and notification order, or a mandatory recall order, shall notify the appropriate person(s) of the order by verified written communication, e.g., telegram, mailgram, or fax. The written communication and any envelope in which it is sent or enclosed shall be conspicuously marked, preferably in bold red ink: “URGENT—[DEVICE CEASE DISTRIBUTION AND NOTIFICATION ORDER] or [MANDATORY DEVICE RECALL ORDER].” Telephone calls or other personal contacts may be made in addition to, but not as a substitute for, the verified written communication, and shall be documented in an appropriate manner.

(c) *Contents.* The person named in the order shall ensure that the notice of a cease distribution and notification order or mandatory recall order:

(1) Is brief and to the point;

(2) Identifies clearly the device, size, lot number(s), code(s), or serial number(s), and any other pertinent descriptive information to facilitate accurate and immediate identification of the device;

(3) Explains concisely the serious, adverse health consequences that may occur if use of the device were continued;

(4) Provides specific instructions on what should be done with the device;

(5) Provides a ready means for the recipient of the communication to confirm receipt of the communication and to notify the person named in the order of the actions taken in response to the communication. Such means may include, but are not limited to, the return of a postage-paid, self-addressed post card or a toll-free call to the person named in the order; and

(6) Does not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message.

(d) *Followup communications.* The person named in the cease distribution

and notification order or mandatory recall order shall ensure that followup communications are sent to all who fail to respond to the initial communication.

(e) *Responsibility of the recipient.* Health professionals, device user facilities, and consignees who receive a communication concerning a cease distribution and notification order or a mandatory recall order should immediately follow the instructions set forth in the communication. Where appropriate, these recipients should immediately notify their consignees of the order in accordance with paragraphs (b) and (c) of this section.

§810.16 Cease distribution and notification or mandatory recall order status reports.

(a) The person named in a cease distribution and notification order issued under §810.10 or a mandatory recall order issued under §810.13 shall submit periodic status reports to FDA to enable the agency to assess the person's progress in complying with the order. The frequency of such reports and the agency official to whom such reports shall be submitted will be specified in the order.

(b) Unless otherwise specified in the order, each status report shall contain the following information:

(1) The number and type of health professionals, device user facilities, consignees, or individuals notified about the order and the date and method of notification;

(2) The number and type of health professionals, device user facilities, consignees, or individuals who have responded to the communication and the quantity of the device on hand at these locations at the time they received the communication;

(3) The number and type of health professionals, device user facilities, consignees, or individuals who have not responded to the communication;

(4) The number of devices returned or corrected by each health professional, device user facility, consignee, or individual contacted, and the quantity of products accounted for;

(5) The number and results of effectiveness checks that have been made; and

(6) Estimated timeframes for completion of the requirements of the cease distribution and notification order or mandatory recall order.

(c) The person named in the cease distribution and notification order or recall order may discontinue the submission of status reports when the agency terminates the order in accordance with §810.17.

§810.17 Termination of a cease distribution and notification or mandatory recall order.

(a) The person named in a cease distribution and notification order issued under §810.10 or a mandatory recall order issued under §810.13 may request termination of the order by submitting a written request to FDA. The person submitting a request shall certify that he or she has complied in full with all of the requirements of the order and shall include a copy of the most current status report submitted to the agency under §810.16. A request for termination of a recall order shall include a description of the disposition of the recalled device.

(b) FDA may terminate a cease distribution and notification order issued under §810.10 or a mandatory recall order issued under §810.13 when the agency determines that the person named in the order:

(1) Has taken all reasonable efforts to ensure and to verify that all health professionals, device user facilities, consignees, and, where appropriate, individuals have been notified of the cease distribution and notification order, and to verify that they have been instructed to cease use of the device and to take other appropriate action; or

(2) Has removed the device from the market or has corrected the device so that use of the device would not cause serious, adverse health consequences or death.

(c) FDA will provide written notification to the person named in the order when a request for termination of a cease distribution and notification order or a mandatory recall order has been granted or denied. FDA will respond to a written request for termination of a cease distribution and notification

or recall order within 30 working days of its receipt.

§810.18 Public notice.

The agency will make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new mandatory recall issued under §810.13. The agency will delay public notification of orders when the agency determines that such notification may cause unnecessary and harmful anxiety in individuals and that initial consultation between individuals and their health professionals is essential.

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